

## PATENT

**REMARKS**

In the Office Action, claims 1-3 and 7-11 are rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,628,774 to Helland et al.

In the Office Action, claims 22-25 are rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,628,774 to Helland et al. in view of U.S. Patent Application No. 2002/0016622 to Janke et al.

In the Office Action, claims 4-6 and 12-15 are rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,628,774 to Helland et al. in view of U.S. Patent No. 6,078,839 to Carson.

In response thereto, claim 2 has been cancelled, claims 1, 3, and 4 have been amended, and new claim 26 has been added. Accordingly, claims 1, 3-15, and 22-26 are now pending.

**Independent Claim 1**

Claim 1 recites a lead body comprising an insulating housing defining an outer surface, a flexible membrane surrounding the insulating housing, a distal circumferential seal attaching a distal portion of the membrane to the outer surface of the insulating housing, and a proximal circumferential seal attaching a proximal portion of the membrane to the outer surface of the insulating housing. The distal circumferential seal and proximal circumferential seal define a sealed space between the inner surface of the membrane and the outer surface of the insulating housing. A lubricious medium is disposed within the sealed space. Flexibility of the membrane and the properties of the lubricious medium enable the membrane to slide over the insulating housing and deform as the insulating housing moves relative to a patient's body tissue. Relative motion between the membrane and the insulating housing reduces abrasive wear of the lead body.

The Helland et al. reference discloses an implantable lead having a composite insulating structure formed from two different insulating materials, one overlying the

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other, which results in a lead having superior overall characteristics. In one embodiment, the implantable lead has a relatively thick silicone insulation tubing and a relatively thin polyurethane insulation tubing. The polyurethane insulation tubing may be disposed over the silicone insulation tubing by first coating the outer surface of the silicone insulation tubing with isopropyl alcohol and then quickly sliding the polyurethane insulation tubing over the silicone insulation tubing.

The Helland et al. reference does not disclose or suggest a distal and proximal circumferential seal to respectively attach a distal portion and proximal portion of the membrane to the outer surface of the insulating housing. Furthermore, the Helland et al. reference does not disclose or suggest the distal circumferential seal and the proximal circumferential seal defining a sealed space between the inner surface of the membrane and the outer surface of the insulating housing. Still further, the Helland et al. reference does not disclose or suggest properties of a lubricious medium enabling the membrane to slide over the insulating housing and deform as the insulating housing moves relative to a patient's body tissue. One of the problems associated with the implantable lead disclosed in the Helland et al. reference is that a lack of distal and proximal seals may cause the isopropyl alcohol to dissipate from the polyurethane insulation tubing/silicone insulation tubing interface prior implantation. As such, the isopropyl alcohol will no longer be present at the interface to act as a lubricious medium to enable the polyurethane insulation tubing to slide over the silicone insulation tubing and deform as the silicone insulation tubing moves relative to a patient's body tissue.

The Carson reference is cited with respect to one of the above referenced obviousness rejections because it supposedly discloses a lubricious medium comprising a medical grade material. In particular, the Office Action states that column 2, lines 50-55 of the Carson reference discloses a lubricious medium composition of a biocompatible material. This portion of the specification is directed to patching an abraded lead with room temperature vulcanization (RTV) biocompatible silicone material. Nowhere does the Carson reference disclose or suggest using the RTV as a lubricious medium. Furthermore, nowhere does the Carson reference disclose or

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suggest a distal and proximal circumferential seal to respectively attach a distal portion and proximal portion of a membrane to the outer surface of the insulating housing.

The Janke et al. reference is cited with respect to one of the above referenced obviousness rejections because it supposedly discloses a fluid lubricious element and a fluid-tight chamber. Paragraph 38 of the Janke et al. reference is directed to coating a piston (150) and/or a portion of a helix (100) with a hydrogel seal (164). The hydrogel seal is adapted to expand upon contact with fluid and fill and seal off an annular gap (156) between the piston and housing (140) such that the hydrogel seal prevents blood flow through an electrode tip.

The Janke et al. reference does not disclose or suggest a distal and proximal circumferential seal to respectively attach a distal portion and proximal portion of the membrane to the outer surface of the insulating housing. Furthermore, the Janke et al. reference does not disclose or suggest a distal circumferential seal and a proximal circumferential seal defining a sealed space between the inner surface of the membrane and the outer surface of the insulating housing. The Janke et al. reference is directed to an expandable seal for sealing a distal portion of a lumen. Still further, claim 1 of the present application recites a first element comprising a distal seal, a second element comprising a proximal circumferential seal, and a third element comprising a lubricious medium. At most, the hydrogel seal of Janke et al. may represent one of the three elements recited in claim 1 of the present application. In other words, the hydrogel seal can not represent all three recited elements.

Accordingly, it is respectfully submitted that claim 1 is in condition for allowance.

**Dependent Claims 3-15 and 22-26**

Claims 3-15 and 22-26 depend from claim 1 and are similarly patentable.

Accordingly, it is respectfully submitted that these claims are in condition for allowance.

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**CONCLUSION**

In light of the above claim amendments and remarks, it is respectfully submitted that the application is in condition for allowance, and an early notice of allowance is requested.

Respectfully submitted,

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